Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume X Issue 6 July 2005

FDA Needs Your Help

The Food and Drug Administration (FDA) needs your help in the post-market surveillance of *in vitro* diagnostic devices (IVD). The following information was provided by the FDA.

Importance of reporting adverse events: An important part of the FDA program for regulation of medical devices is surveillance of problems after entry of the device into the marketplace. Surveillance is performed to assure safety and timely identification of performance problems. When problems are identified, FDA works with manufacturers to take necessary action to protect the public health. A cadre of analysts reviews incoming adverse event reporting data. Based on information obtained from these reports, the agency may use a variety of educational (publications, public health notices, workshops, and joint communications with CDC — MMWR reports) and enforcement tools (recalls, directed inspections, and labeling changes) to address the problems.

Required reporting of adverse events that result in serious patient injury or death: When information reasonably suggests that a laboratory product or instrument has or may have caused or contributed to a patient death or serious patient injury, the FDA requires manufacturers, importers, health care professionals in hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report MUST be made both to the FDA and the device manufacturer. If the event is serious patient injury, the report may be made to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA. Reports must be submitted on FDA Form 3500A (http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html) or an electronic equivalent as soon as practicable, but no later than 10 working days from the time personnel become aware of the event.

Serious patient injury definition: FDA defines "serious patient injury" as one that is life threatening, or results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Inaccurate test results produced by an IVD and reported to the health care professional may lead to medical situations that fall under the definition of serious injury as described above and, therefore, are reportable events.

Voluntary reporting of other adverse events: The FDA

continued on page 2

Inside This Issue

Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

- Anemia
- ANA
- Bioterrorism Event Mgmt
- Bleeding Disorders
- Chlamydia
- Diabetes
- Group A Strep Pharyngitis
- Hepatitis
- HIV
- Infectious Diarrhea
- Intestinal Parasites
- Lipid Screening
- PAP Smear
- Point-of-Care Testing
- PSA
- Rash Illness
- Red Cell Transfusion
- Renal Disease
- STD
- Thyroid
- Tuberculosis
- Urinalysis
- Wellness

FDA Needs Your Help, continued from page 1

has a procedure for medical personnel to voluntarily report device-related adverse events that may be related to a laboratory test and do not fall under FDA required reporting. This procedure applies to adverse events (device malfunctions, patient injuries and potential patient injuries that do not qualify as serious injuries) noted in the course of clinical care, not events that occur in the course of clinical trials or other studies. Examples of events that should be voluntarily reported to the FDA include a test kit not performing up to the expectations outlined in the package insert, or a test kit that does not match the information outlined in the package insert, etc. Information on how to submit a voluntary report is provided at http://www.fda.gov/medwatch/report/hcp.htm.

Laboratory policies: The laboratory should have written procedures for 1) the identification and evaluation of adverse patient events, 2) the timely submission of required medical device reports, and 3) compliance with record keeping requirements. Further details are available at http://www.fda.gov/cdrh/mdruf.pdf. Laboratories that are part of a larger organization (e.g., hospital laboratories) should document participation in the overall institutional Medical Device Reporting (MDR) process. The laboratory should educate its personnel in the FDA MDR requirements.

Additional information is available on the following websites:

http://www.fda.gov/cdrh/mdr/index.html
http://www.fda.gov/cdrh/mdr/mdr-general.html

Emergency Response Coordination

The effective planning and coordination of bioterrorism emergency response activities have become a primary concern nationally since the terrorist attacks of 9/11 and anthrax attack in October 2001. Within the Washington State Department of Health (DOH), planning for emergency preparedness and response has led to a regional system that allows for both efficient and coordinated emergency response.

In order to effectively manage emergency response activities and planning, the State of Washington has been divided into nine distinct regions. Regional Emergency Response Coordinators (RERCs) have been hired from each of these regions who have a lead role in the emergency response activities of their region and who, with the help of local health department personnel, coordinate and plan emergency response activities. There are also four State Emergency Response Coordinators (SERCs) in place who oversee and coordinate the activities of the nine RERCs. Tables 1 and 2 on page 3 list contact information for RERCs and SERCs in Washington State.

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Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page: http://www.doh.wa.gov/lqa.htm
PHL home page:
http://www.doh.wa.gov/EHSPHL/PHL/default.htm

Notifiable Conditions for Laboratories

Local Health Jurisdiction Contacts

see pages 4 and 5

Emergency Response Coordination, continued from page 2

Table 1 - Washington State Regional Emergency Response Coordinators

Region	Counties	Coordinator	Phone	E-mail
1	Island, San Juan, Skagit, Snohomish*, Whatcom	T.J. Harmon	(425) 339-8708	tharmon@shd.snohomish.wa.gov
2	Kitsap*, Clallam, Jefferson	Brian Arcement	(360) 337-5267	arcemb@health.co.kitsap.wa.us
3	Lewis, Grays Harbor, Mason, Pacific, Thurston*	Michael Presswood	(360) 786-5581 x 7050	presswm@co.thurston.wa.us
4	Clark*, Cowlitz, Skamania, Wahkiakum	Richard Konrad	(360) 397-8072	richard.konrad@clark.wa.gov
5	Tacoma-Pierce*	Cindy Miron	(253) 798-6556	cmiron@tpchd.org
6	Public Health Seattle-King County*	Byron Byrne Mark Rowe Cynthia Dold, Hospital EPR Contact	(206) 205-6277 (206) 205-8625 (206) 205-0456	byron.byrne@metrokc.gov mark.rowe@metrokc.gov cynthia.dold@metrokc.gov
7	Chelan-Douglas*, Grant, Kittitas, Okanogan	Chuck Johnson	(509) 886-6421	chuck.johnson@cdhd.wa.gov
8	Benton-Franklin*, Klickitat, Walla Walla, Yakima	Leslie Koenig	(509) 586-0673	lesliek@bfhd.wa.gov
9	Spokane*, Adams, Asotin, Columbia, Garfield, Lincoln, NE Tri, Whitman	Richard Green	(509) 232-1703	rgreen@spokanecounty.org

*Designated Lead Agency for Region

Table 2 - Washington State Emergency Response Coordinators

Regions	Coordinator	Phone	E-mail
1, 2, 6	Jennifer Foster	(253) 395-6716	jennifer.foster@doh.wa.gov
3, 4, 5	Johnny Clark	(360) 236-4623	johnny.clark@doh.wa.gov
7, 8	Rita Konzal	(509) 397-3559	rita.konzal@doh.wa.gov
9	Valerie Munn	(509) 456-2726	valerie.munn@doh.wa.gov

Notifiable Conditions & Washington's Laboratories

Washington State Department of Health

The following laboratory results (preliminary or confirmed) are notifiable to public health authorities in Washington in accordance with WAC 246-101. Timeframes for notification are indicated in footnotes. **Immediately notifiable results are indicated in bold**. Information provided must include: specimen type; name and telephone number of laboratory; date specimen collected; date specimen received; requesting health care provider's name and telephone number or address; test result; name of patient (if available) or patient identifier; sex and date of birth or age of patient (if available).

Arboviral disease (West Nile virus disease, dengue, Eastern & Western equine encephalitis, etc.) (detection of viral antigen, antibody, or nucleic acid) 2*

Blood lead level (elevated) 2&i

Blood lead level (non-elevated) M&i

Bordetella pertussis 2*

Brucella 2*!

CD4+ counts <200 or <14% M&ii

Chlamydia trachomatis 2*

Clostridium botulinum **I*!**

Corynebacterium diphtheriae 2*!

Cryptosporidium parvum 2*

Cyclospora cayetanensis 2*!

Disease of suspected bioterrorism origin I*!
Anthrax *(Bacillus anthracis)* I*!
Smallpox (Variola virus) I*!

Escherichia coli (Shiga-like toxin only) 2*!

Francisella tularensis 2*!

Hepatitis A (IgM +) 2*

Hepatitis B (detection of viral antigen, antibody, or nucleic acid) M*

Hepatitis C (detection of antibody or nucleic acid) M*

Human immunodeficiency virus (Western Blot, P-24 antigen, or viral culture) 2&ii

Human immunodeficiency virus M&ii (RNA or DNA nucleic acid tests)

Listeria monocytogenes 2*

Mycobacterium tuberculosis 2&iii!@

Neisseria gonorrhoeae 2*

Neisseria meningitidis 2*!

Rabies I*

Rubeola I*!

Salmonella species 2*!

Shigella species 2*!

Treponema pallidum 2*!

Rare diseases of public health significance I*

Vibrio cholerae **I*!**

Yersinia pestis **I*!**

CODE LEGEND

I Immediately notifiable
2 Notifiable within 2 work days
M Notifiable on a monthly basis
* Notifiable to the local health jurisdiction of the patient's residence
&i Notifiable to DOH Lead Program **360-236-4252**
&ii Notifiable to DOH IDRH Assessment **360-236-3419**
&iii Notifiable to DOH TB Reporting Line **206-418-5472**
or TB Reporting Fax Line **206-418-5545**
! Specimen submission required
@ Antibiotic sensitivity testing (first isolates only)

To report a Notifiable Condition, contact the local health jurisdiction of the patient's residence, unless the condition is reportable directly to DOH. If the patient's local health jurisdiction is unknown, please notify the local health jurisdiction of the health care provider that ordered the diagnostic test.

If no one is available at the local health jurisdiction and a condition is immediately notifiable, please call 1-877-539-4344

For more information, please see WAC 246-101 or www.doh.wa.gov/notify

Local Health Jurisdiction Notifiable Condition Contacts

In accordance with Washington State Law (www.doh.wa.gov/notify/other/legal.htm), public health and health care professionals should report notifiable conditions to the local health jurisdiction in the county of the patient's residence. Disease reporting telephone numbers are provided below. For a complete list of notifiable conditions for health care providers, hospitals, and laboratories, please refer to the posters section at www.doh.wa.gov/notify.

LOCAL HEALTH JURISDICTION	PHONE	AFTER HOURS
Adams County Health District	509-659-3315	509-659-3315
Asotin County Health District	509-758-3344	208-798-2648
Benton-Franklin Health District	509-547-9737, x226	509-543-3851
Chelan-Douglas Health District	509-886-6400	509-665-2202
Clallam County Health Department	360-417-2274	360-415-2005
Clark County Health Department	360-397-8408	888-727-6230
Columbia County Health District	509-382-2181	911
Cowlitz Health District	360-414-5590	360-636-9595
Garfield County Health District	509-843-3412	509-843-3494
Grant County Health District	509-754-6060	509-398-2083
Grays Harbor Health Department	360-532-8631	360-581-1401
Island County Health Department	360-679-7351	360-679-9567
Jefferson County Health Department	360-385-9400	360-415-2005
King County (Public Health Seattle & King County)		
HIV/AIDS	206-296-4645	206-726-2128
STDs	206-731-3954	206-726-2128
TB	206-731-4579	206-726-2128
Other Communicable Diseases	206-296-4774	206-296-4774
Message	206-296-4782	206-296-4782
Kitsap County Health Department	360-337-5235	911
Kittitas County Public Health Department	509-962-7515	911
Klickitat County Health Department	509-773-4565	911
Lewis County Dept. of Human Services	360-740-1257	360-740-1275
Lincoln County Health Department	509-725-1001	509-725-3501
Mason County Health Department	360-427-9670, x274	911
Northeast Tri-County Health District		
Ferry County	509-775-3111	911
Pend Oreille County	509-447-3131	911
Stevens County	509-684-5048	911
Okanogan County Health District	509-422-7140	911
Pacific County Health Department	360-875-9343	360-875-9397
Pierce County Health Department	253-798-6410	253-798-6534
San Juan County Health Department	360-378-4474	360-410-1676
Skagit County Health Department	360-336-9397	360-336-9397
Skamania County Health Department	800-996-2526	888-727-6230
Snohomish County Health District	425-339-5278	425-339-5295
Spokane County Health District	509-324-1449	509-324-1500
Thurston County Health Department	360-786-5470	911
Wahkiakum County Health Department	360-795-6207	360-795-6207
Walla Walla Health Department	509-527-3290	509-527-3290
Whatcom County Health Department	360-676-4593	360-738-2503
Whitman County Health Department	509-397-6280	509-397-6280
Yakima County Health District	509-249-6541	509-575-4040, #1

Washington State Department of Health

If no one is available at the local health jurisdiction and a condition is immediately notifiable, please call the Department of Health 24-hour reporting line: **(877) 539-4344**

Waived Testing Helpful Hints

√ When billing for waived tests or provider performed microscopic procedures performed in your laboratory, be sure to use the correct CPT code **and modifier,** if indicated, for that particular test and/or test kit.

√ A listing of the current approved CPT codes for waived test kits and microscopic procedures can be found on the Laboratory Quality Assurance Website:
http://www.doh.wa.gov/lqa.htm
Select the side bar: MTS Laws

√ Insurance claims will most likely be rejected if you are not using the proper CPT code for the waived tests and provider performed microscopic procedures done in your laboratory.

Calendar of Events

PHL Training Classes:
(http://www.doh.wa.gov/EHSPHL/PHL/train.htm)

Basic Microscopy
July 13 Shoreline

Northwest Medical Laboratory Symposium
October 26-29, 2005 Seattle

12th Annual Clinical Laboratory Conference
November 7, 2005 Seattle

2006 WSSCLS/NWSSAMT Spring Meeting
April 2006 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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